

REMARKS

FORMAL MATTERS:

With entry of this paper, claims 1, 3-13, 15-19 and 43-47 are pending in the instant application. Claim 43 has been cancelled without prejudice. Claims 12 and 13 have been amended to address formalities according to instructions in the pending Office Action.

CLAIM OBJECTIONS:

Claims 6, 12 and 13 are objected to. According to the Office Action, the phrase “the free margin” of claim 6 lacks clear antecedent basis. Applicants respectfully disagree. Claim 6 recites “...the free margin of the prolapsing leaflet... .” This phrase finds antecedent basis in base claim 1, which recites beginning on line 7, “...a free margin of the prolapsing segment...” Applicants respectfully request guidance as to how the Examiner proposes claim 6 be amended so as to not create confusion.

Claims 12 and 13 have been amended as suggested by the Examiner in the Office Action. Applicants respectfully request the objections to the claims be withdrawn.

REJECTIONS UNDER §112 – FIRST PARAGRAPH

Claim 43 has been rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the written description requirement. According to the Office Action the language, "the structure is configured to be non-attachable to an annulus of the valve" lacks original support and appears to be nonenabled.

Applicant does not concede that the argument presented in the Office Action is correct, or reaches a logical conclusion. Moreover, claims 43 and 44 were the only new claims presented on March 24, 2006, and Applicant was under the impression that the claims received the full attention of the Examiner at that time. Applicant respectfully directs the Examiner to MPEP 707.07(g). However, in the

interest of comity and judicious prosecution, Applicant has cancelled claim 43. In view of the cancellation of claim 43, Applicant respectfully submits that the objection to the specification is moot.

Claims 1, 5-9, 12, 13, 15-19, and 43-47 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. According to the Office Action, it is unclear what "an effective valve area" is because it has not been clearly and adequately described in the specification. Applicant respectfully disagrees.

Applicant apologizes for any confusion in not repeating the support for the claim amendments presented in the preliminary amendment. Support for the amendments was presented in the prior response to final. The support for the prior amendments may be found throughout Applicant's specification, particularly in paragraphs 23, 39 and 45, and claim 2 of Applicant's originally filed application. With regard to the phrase, "an effective valve area," Applicant respectfully directs the Examiner to paragraph 39, which reads in relevant part:

"Unlike many prior art modalities of valve prolapse repair, the subject devices facilitate proper leaflet coaptation without affecting the mobility of the opposing leaflet (i.e., the leaflets are not connected together--unlike with edge-to-edge repair) and **without reducing the effective valve area (i.e., the area of the valve orifice is maintained--unlike with edge-to-edge repair)**." (Emphasis added)

Applicant respectfully submits that the terms used are terms of art well understood by those of skill in the art. Applicant's specification not only supports the claim language at issue but does so *ipsis verbis*. Moreover, figures 3-7 of Applicant's specification illustrate the effect of the repair from various aspects. Accordingly, Applicant respectfully requests the present rejection be withdrawn.

REJECTIONS UNDER §112 – SECOND PARAGRAPH

Claims 1, 5-9, 12, 13, 15-19, and 43-47 have also been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. According to the Office Action, the Examiner asserts that the

claim scope is unclear in that it is not clear what would fall within the claim scope and what would not because the “effective valve area” has not been adequately explained. Applicant respectfully disagrees.

As explained above, a precise definition of “effective valve area” is provided in Applicant’s originally filed specification. The definition is provided using terms well known to those of skill in the art and supported with illustrations. Applicant respectfully submits that the originally filed specification fully enables the claims as written. Moreover, Applicants respectfully point out that it is not necessary for Applicants specification to instruct the reader as to what is already known to those of skill in the art. Notwithstanding any other disclosure in Applicant’s specification, Applicant provides the reader with suitable materials, fixation components and methods, diagrams and definitions as to how Applicant’s invention is to be applied to a heart valve. Given such an extensive disclosure, Applicant respectfully submits that one of skill in the art would readily understand how Applicant’s invention would be made and used. Accordingly, Applicant respectfully requests the instant rejection be withdrawn.

REJECTIONS UNDER §102 – DARDICK ET AL.

Claims 1, 2, 5, 7-9, 12, 16-19 and 43-47 have been rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Dardik *et al.* (U.S. Patent No. 3,988,782). Applicant respectfully disagrees.

In order to anticipate Applicants’ invention, a prior art document must contain all of the elements and limitations of the Applicants’ rejected claim(s). There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Research Found. v. Genetech, Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). Applicants respectfully traverse the anticipation rejection as to Dardik, as the cited reference fails to teach a material capable of providing, *inter alia*, the stable coaptation surface and resistance to vassicular pressures of Applicants’ claimed invention. Accordingly, Applicants respectfully request the instant rejection be withdrawn.

According to the Office Action, Dardik anticipates the claim language as the graft of Dardik is considered by the Examiner to be at least semi-rigid to the extent claimed because it is hardened and

even provided with a backing to improve its integrity. In other words, The Examiner believes it is capable of being attached to a leaflet to the extent that the functional language implies; see Figures 5 and 6 and column 5, line 15 to column 6, line 61. The rejection concludes with the Examiner asserting that the Dardik material is rigid to semi-rigid to the extent required by the claims because it reasonably appears to be able to function as claimed in that it is to be used in a similar environment.

Applicants respectfully submit that Dardik can not anticipate Applicants amended claims because the grafts discussed in Dardik lack the physical characteristics necessary to provide the structural elements required to perform as a prosthetic for valve repair as claimed by Applicants. In support, Applicants respectfully direct the Office to the Dardik specification itself:

"In our copending Application Ser. No. 543,462 filed Jan. 23, 1975, methods of treating the umbilical cord chemically have been disclosed. However, the previous application was directed primarily toward the use of umbilical cord vessels in vascular surgery, such use requiring that the umbilical cord vessels withstand pulsatile pressures. Synthetic mesh reinforcement of the cord vessels was disclosed. The present invention is directed toward a wider spectrum of uses in which the strength requirements are less severe."

Col. 5, lines 44-51.

Applicants submit that as Dardik's treated umbilical chord is admittedly incapable of serving directly as a vascular replacement because the material is unable to withstand the pulsatile pressures involved, the same material certainly cannot perform as a heart valve prosthetic where the pulsatile pressures of the vascular system are even more severe. As the Office Action has provided no evidence indicating why Dardik is incapable of accurately characterizing his disclosure and the Patent Office is better qualified to do so, Applicant respectfully submits that the present Office Action fails to present a *prima facie* case of anticipation as the assertions presented in support of the instant rejection are in direct conflict with the stated limitations of the Dardik reference.

Figures 5 and 6, and column 5, line 15 to column 6, line 61 of Dardik are cited as support for the assertions upon which the present rejection is based. Applicant respectfully points out that these citations do nothing to support the claim rejections. As to figures 5 and 6, figure 5 appears to show a flat piece of material and nothing more. There is no indication as to how such a piece of material is to

be attached to a prolapsing leaflet or otherwise meet the limitations of Applicant's claims required to repair a heart valve. Figure 6 also has nothing to do with valve repair, but rather shows a patch for a blood vessel, not a heart valve. In fact, Figure 6 supports Dardik's contention that the discussed patch can not be used in the heart, and is affixed to the vessel on all 4 sides making it impossible to act as a valve. Finally, the Office Action refers to column 5, line 15 to column 6, line 61, however this disclosure has nothing to do with heart valve repair, but rather discusses repair of blood vessels. More particularly, nothing in the cited reference teaches:

"...a structure configured for attachment to the prolapsing leaflet at the prolapsing segment without affecting the effective valve area, said structure defining a stable coaptation surface against which an opposing leaflet reversibly coapts during systolic contraction of the heart whereby the coaptation between the leaflets is normalized, the coaptation surface configured to extend freely beyond a free margin of the prolapsing segment when the structure is operatively implanted within the valve..."

required by Applicant's claims. Therefore the reference fails to teach each element of Applicant's claims and can not be anticipatory to them.

Finally, Dardik provides absolutely no enablement for the heart valve prosthetic device the Office Action seeks to attribute to it. In order to be anticipating, a prior art reference must be enabling so that the claimed subject matter may be made or used by one skilled in the art. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003); *Helifix, Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed. Cir. 2000); *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1479 (Fed. Cir. 1986). Prior art is not enabling so as to be anticipating if it does not enable a person of ordinary skill in the art to carry out the invention. See *Elan Pharms., Inc. v. Mayo Found.*, 346 F.3d 1051, 1057 (Fed. Cir. 2003).

Nowhere in Dardik is there any disclosure identifying how the devices discussed could be adapted for use in the heart, or how it might be applied to a prolapsing leaflet of a valve. Therefore, as the instant rejection fails to present a *prima facie* case, fails to teach each element of Applicant's

pending claims and is not enabled for the suggested purpose, Applicant respectfully submits Dardik can not anticipate Applicant's invention and the present rejection should be withdrawn.

REJECTIONS UNDER §103(A)

Claims 13 and 15 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dardik *et al.* The Office Action maintains that Dardik teaches Applicant's invention with the exception of particular dimensions. Applicants respectfully disagree.

A *prima facie* case for obviousness under §103 requires the Office to show, *inter alia*, that the references cited against Applicants teach or suggest all claim limitations of the rejected claim(s). *In re Royka*, 180 USPQ 580 (CCPA 1974); and MPEP §2143.03. As Applicants' previously noted in responding to the anticipation rejection as to Dardik, above, Dardik fails to teach all claim limitations of Applicants' amended claims. Applicants submit that comments as to relative dimensions are moot. Accordingly, Applicants traverse the rejection as to Dardik under §103 and respectfully request the rejection be withdrawn.

Moreover, Applicants respectfully note that Dardik teaches away from the proposed combination (see Dardik at Col. 5, lines 44-51, and explanations provided in response to the §102 rejection as to Dardik, above). Combination of a reference that teaches away is improper and fails to establish a *prima facie* case of obviousness. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). Therefore, Applicant respectfully request the rejection as to Dardik under §103 be withdrawn.

CONCLUSION

Applicant is not aware of any co-pending applications that set forth similar subject matter to the present claims.

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number MSSM-001.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date:

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By:

Karl Bozicevic
Registration No. 28,807

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, California 94303
Telephone: (650) 327-3400
Facsimile: (650) 327-3231